

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK A/S,

Plaintiff and Counterdefendant,

v.

AVENTIS PHARMACEUTICALS INC,
SANOFI-AVENTIS, and AVENTIS
PHARMA DEUTSCHLAND GMBH,

Defendants and Counterplaintiffs.

Case No. 05-645 (SLR)

**REDACTED
PUBLIC VERSION**

DECLARATION OF ANNE SHEA GAZA

I, Anne Shea Gaza, declare as follows:

1. I am a member of the Delaware Bar, an associate of the firm of Richards, Layton & Finger, P.A. and counsel for plaintiff Novo Nordisk A/S. I make this affidavit in support of Novo Nordisk A/S' Memorandum in Opposition to Aventis's Motion for Leave to File and Amended Answer and Counterclaims.
2. Attached hereto as Exhibit A is a true and correct copy of a November 1, 2006 letter from Eric Moran to Stephen Vitola;
3. Attached hereto as Exhibit B is a true and correct copy of documents bearing production numbers NN 034503 through NN 034505 [Notice of allowability];
4. Attached hereto as Exhibit C are true and correct copies of selected excerpts of the transcript of the deposition of Marc Began conducted on October 3, 2006;
5. Attached hereto as Exhibit D is a true and correct copy of an August 7, 2006 letter from Eric Moran to Stephen Vitola;

6. Attached hereto as Exhibit E is a true and correct copy of the selected excerpts from the file history of U.S. Patent No. 6,562,011 bearing production numbers SAN00762393 through SAN00762398 [produced in its entirety to SAN00762586];

7. Attached hereto as Exhibit F is a true and correct copy of an August 9, 2006 letter from Eric Moran to Stephen Vitola;

8. Attached hereto as Exhibit G is a true and correct copy of the front page of U.S. Patent No. 6,562,011 which was produced by Aventis bearing production numbers SAN00823009 through SAN00823014;

9. Attached hereto as Exhibit H is a true and correct copy of selected excerpts from the file history of U.S. Patent No. 6,562,011 bearing production numbers SAN00828212 through SAN00828405;

10. Attached hereto as Exhibit I is a true and correct copy of the front page of U.S. Patent No. 6,146,361 which was produced by Aventis bearing production numbers SAN00760915 through SAN00760923;

11. Attached hereto as Exhibit J is a true and correct copy of the front page of U.S. Patent No. 4,936,833 which was produced by Aventis bearing production numbers SAN00762258 through SAN00762270;

12. Attached hereto as Exhibit K is a true and correct copy of the front page of U.S. Patent No. 5,554,125 which was produced by Aventis bearing production numbers SAN00762354 through SAN00762372;

13. Attached hereto as Exhibit L is a true and correct copy of the front page of U.S. Patent No. 5,549,575 which was produced by Aventis bearing production numbers SAN00762343 through SAN00762353;

14. Attached hereto as Exhibit M is a true and correct copy of the front page of U.S. Patent No. 5,137,511 which was produced by Aventis bearing production numbers SAN00762289 through SAN00762307; and

15. Attached hereto as Exhibit N is a true and correct copy of a September 6, 2006 letter from James McCarthy to Stephen Vitola.

I DECLARE UNDER THE PENALTY OF PERJURY THAT THE ABOVE IS TRUE AND CORRECT.

Date: November 22, 2006


Anne Shea Gaza

EXHIBIT A



McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive 312 913 0001 phone
Chicago, Illinois 60606-6709 312 913 0002 fax
www.mbhblaw.com

November 1, 2006

VIA FACSIMILE
212 354 8113

Stephen J. Vitola
White & Case LLP
1155 Avenue of the Americas
New York, NY 10036-2787

Re: **Novo Nordisk A/S v. sanofi-aventis et al.**
Civil Action No. 05-00645 SLR

Dear Steve:

Pursuant to Local Rule 7.1.1, please find enclosed Aventis's Second Consolidated and Amended Answer and Counterclaims. Aventis intends to file the attached pleading on Monday, November 6, 2006. Please advise before then whether you will consent to or oppose our motion for leave to file Aventis's Second Consolidated and Amended Answer and Counterclaims.

Please note that the attached pleading includes references and quotations from Marc Began's deposition. We do not believe these references or quotations include any confidential information; however, Novo designated Mr. Began's entire deposition transcript as highly confidential. Before November 6, 2006, please advise whether you would like us to file the attached pleading under seal. Please note, any motion for leave to amend that we will file regarding the attached pleading may include the same references and quotations from Mr. Began's deposition.

Regards,

A handwritten signature in black ink, appearing to read 'ER Moran'.

Eric R. Moran
312 913 3302 direct
moran@mbhb.com

Enclosure

EXHIBIT B



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
A Division of the United States Department of Commerce
Washington, D.C. 20591
www.uspto.gov

APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,741	07/06/1999	THOMAS BUCH-KASPERSEN	5533-200-US	7085
24137	294	05/16/2002		
PATENT DEPARTMENT SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP FOUR TIMES SQUARE NEW YORK, NY 10036			EXAMINER SERMONS, KEVIN C	
			ART UNIT 3703	PAPER NUMBER
DATE MAILED: 05/15/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-POC (Rev. 07-01)

NN 034503

N K

Notice of Allowability	Application No.	Applicant(s)
	09/348,748	BUCH-RASMUSSEN ET AL
	Examiner	Art Unit
	Kevin C. Simmons	3763

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address—
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included
herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. THIS
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative
of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to 1/22/02.
2. The allowed claim(s) is/are 1-11.
3. The drawings filed on 1/22/02 are accepted by the Examiner.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some*
 - c) None
 of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

5. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) The translation of the foreign language provisional application has been received.
6. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121

Applicant has THREE MONTHS FROM THE 'MAILING DATE' of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

7. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. CORRECTED DRAWINGS must be submitted.

- (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-848) attached
 - 1) hereto or 2) to Paper No. _____.
- (b) Including changes required by the proposed drawing correction filed _____ which has been approved by the Examiner.
- (c) Including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsman.

9. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

<input type="checkbox"/> Notice of References Cited (PTO-892)	<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-848)	<input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.
<input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____.	<input type="checkbox"/> Examiner's Amendment/Comment
<input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	<input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance
	<input type="checkbox"/> Other

Application/Control Number: 09/349,748
Art Unit: 3763

Page 2

DETAILED ACTION

Allowable Subject Matter

Claims 34-44 are allowable over the prior art of record at the time the invention was made.

The following is an examiner's statement of reasons for allowance: Claims 34, 37, 43 and 44 are allowable over the prior art of record because the prior art does not disclose or render obvious the combination of a first or second coupling means which comprises a snap lock for assisting in coupling or uncoupling of a needle assembly from a cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, thus preventing the cartridge assembly from moving axially with respect to the dosage assembly.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Simons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS
Kevin C. Simons
Patent Examiner
1/23/03

BAC
BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER: 3700

EXHIBIT C

REDACTED
IN ITS
ENTIRETY

EXHIBIT D



McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive 312 913 0001 phone
Chicago, Illinois 60606-5709 312 913 0002 fax
www.mbhblaw.com

August 7, 2006

VIA OVERNIGHT COURIER

Stephen J. Vitola
White & Case LLP
1155 Avenue of the Americas
New York, NY 10036-2787

Re: **Novo Nordisk A/S v. sanofi-aventis et al.**
Civil Action No. 05-00645 SLR

Dear Steve:

Please find enclosed additional Aventis production documents and things. Because of the large number of documents in our production, we have provided these documents on an external USB hard drive. The USB hard drive is "plug and play" and no drivers or software should be required to access the files stored thereon.

We have included the following ranges of documents on the enclosed hard drive:
SAN00100001 through SAN00184310; SAN00300001 through SAN00327077;
SAN00200001 through SAN00255514; SAN00400001 through SAN00457077;
SAN00500001 through SAN00587677; SAN00700001 through SAN00764315; and load files. Please note the gaps in Bates numbers are intentional and were necessary in order to produce such a large number of documents at one time.

Avantis's CONFIDENTIAL and HIGHLY CONFIDENTIAL—OUTSIDE COUNSEL EYES ONLY documents are being produced pursuant to Local Rule 26.2 until a protective order is entered. Under Local Rule 26.2, disclosure of these documents should be limited to members and employees of Novo's outside trial counsel who have entered an appearance or have been admitted pro hac vice in this litigation. Avantis's HIGHLY CONFIDENTIAL documents shall not be shared with anyone at Novo at any time, under any circumstances.

Aug-07-06 17:27

From:McDONNELL BOEHNEN HULBERT & BERGHOFF

+13129130002

T-380

P-03/03 F-736

The enclosed documents include the vast majority of our production documents. Due to the large number of documents in the current production, however, we will also be producing some additional documents in the next few days. As always, we will continue to supplement our production as more documents become available.

Regards,



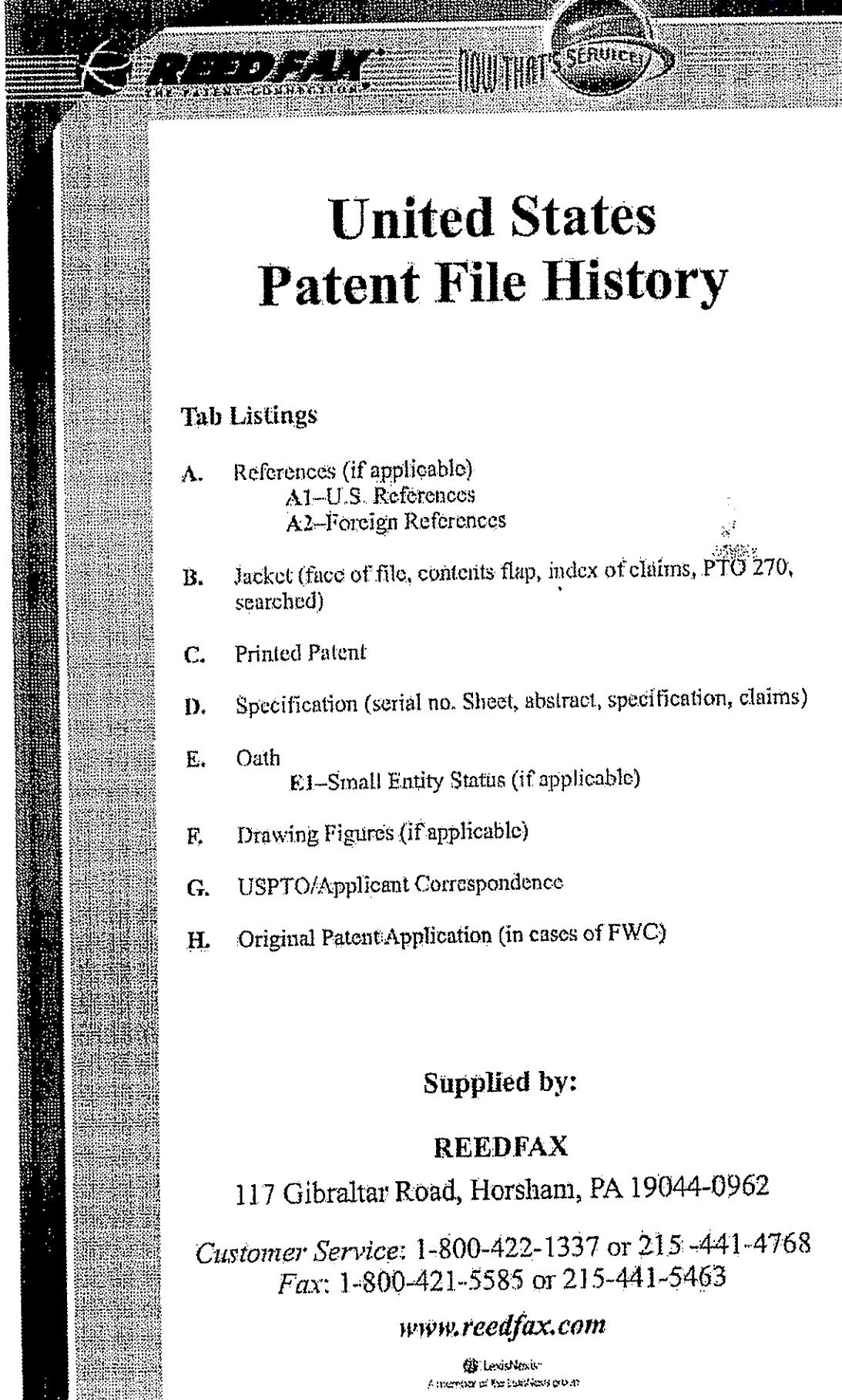
Eric R. Moran
312 913 3302 direct
moran@mbhb.com

encl.

6

8

EXHIBIT E



Tab Listings

- A. References (if applicable)
 - A1—U.S. References
 - A2—Foreign References
- B. Jacket (face of file, contents flap, index of claims, PTO 270, searched)
- C. Printed Patent
- D. Specification (serial no. Sheet, abstract, specification, claims)
- E. Oath
 - E1—Small Entity Status (if applicable)
- F. Drawing Figures (if applicable)
- G. USPTO/Applicant Correspondence
- H. Original Patent Application (in cases of FWC)

Supplied by:

REEDFAX

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SAN00762393

100-1000

604	232	Subclass	ISSUE CLASSIFICATION
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45-8LR Document 118 Filed 11/3/18

2006 Page 17
PATENT NUMBER

U.S. UTILITY PATENT APPLICATION

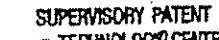
O.I.P.E.	PATENT DATE
PL440	MAY 13 2003
SCANNED <u>A.G. (S.A. M.T.)</u>	

SECTOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
	621	1	3-167	1011201015

FILED WITH: DISK (CRF) FICHE
(Attached in pocket on right inside back)

PREPARED AND APPROVED FOR ISSUE

ISSUING CLASSIFICATION

TERMINAL DISCLAIMER	DRAWINGS			CLAIMS ALLOWED					
	Sheets Drawn	Figs. Drawn	Print Fig	Total Claims	Print Claim for D.G.				
<input type="checkbox"/> a) The term of this patent subsequent to _____ (date) has been disclaimed.	 <small>Karen C. Harmon</small> <small>(Assistant Examiner)</small> <small>(Date)</small>			NOTICE OF ALLOWANCE MAILED  <small>9-20-02</small>					
<input type="checkbox"/> b) The term of this patent shall not extend beyond the expiration date of U.S. Patent No. _____ <small>_____</small> <small>_____</small>	BRIAN L. CASLER SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700  <small>(Primary Examiner)</small> <small>9/16/02</small> <small>(Date)</small>			ISSUE FEE <table border="1"> <tr> <td>Amount Due</td> <td>Date Paid</td> </tr> <tr> <td>\$1280.00</td> <td>12-18-02</td> </tr> </table>		Amount Due	Date Paid	\$1280.00	12-18-02
Amount Due	Date Paid								
\$1280.00	12-18-02								
<input type="checkbox"/> c) The terminal _____ months of this patent have been disclaimed.	 <small>J. Green</small> <small>(Legal Instruments Examiner)</small> <small>9-22-02</small> <small>(Date)</small>			ISSUE BATCH NUMBER <small>9-22-02</small>					
WARNING: The information disclosed herein may be restricted. Unauthorized disclosure may be prohibited by the United States Code Title 35, Sections 122, 181 and 358. Protection outside the U.S. Patent & Trademark Office is restricted to authorized applicants and contractors only.									

WARNING:

The information disclosed herein may be restricted. Unauthorized disclosure may be prohibited by the United States Code Title 35, Sections 122, 181 and 388. Possession outside the U.S. Patent & Trademark Office is restricted to authorized employees and contractors only.

Form 570-5324 (1-54) Rev. 5-63, 581
(Rev. 5-63)

CHANGES IN FILE

1. (ABEL AREA)

(EACCEV)

SAN00762394

PATENT APPLICATION

09348536

U.S. PTO

09/348536

07/07/99

INITIALS M.T.W.

CONTENTS

Date received (Incl. C. of M.) or Date Mailed	Date received (Incl. C. of M.) or Date Mailed
1. Application	8/15/99
2. Unsigned Dec	42. _____
3. Dec + Surcharge	43. _____
4. Rec'd Appl W	44. _____
5. Rec'd Appl B	45. _____
6. Rec'd Appl C	46. _____
7. Rec'd Appl D	47. _____
8. (Ans) (Ans)	48. _____
9. (Ans)	49. _____
10. Reg. Rec'd CFR	50. _____
11. Ext. of Time (3)	51. _____
12. And C	52. _____
13. FINAL REJECT	53. _____
14. Ext. 2 mo	54. _____
15. Reg. for Rec'v. Notice, 13/11/01	55. _____
16. REJECTION	56. _____
17. Notice of Appeal	57. _____
18. Ext. of Time (3)	58. _____
19. Reg. for Rec'v.	59. _____
20. (Ans) (Ans)	60. _____
21. Amend D (N.F.)	61. _____
22. EXAMINER'S AMEND	62. _____
23. QUERY	63. _____
24. REG. PUR/ CRR	64. _____
25. Priority	65. _____
26. 651B CHG OF ADD	66. _____
27. Fwd. Drawings 1 to 50	67. _____
28. _____	68. _____
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SAN00762395

ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEES DETERMINATION	MTH		7/14/99
O.P.E. CLASSIFIER	M-TW	5A	7-7-99
FORMALITY REVIEW	RF	70556	8-5-99
	RF	70556	10-20-99

INDEX OF CLAIMS

✓ Rejected
 = Allowed
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N Non-elected
 I Interference
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Claim	Date
1	7/14/99
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If more than 150 claims or 10 actions
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(1 EFT INSIDE)

SAN00762396

SEARCHED

Class	Sub.	Date	Exmr.
604	200-201 228 232-234	1/21/00	KCS
Same	as above	1/17/02	ICCS

**SEARCH NOTES
(INCLUDING SEARCH STRATEGY)**

	Date	Exmr.
M. Bockelman	1/21/00	KCS

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
Same as	above	1/17/02	ICCS

(RIGHT OUTSIDE)

SAN00762397

(12) United States Patent
Buck-Rasmussen et al.(10) Patent No.: US 6,562,011 B1
(45) Date of Patent: May 13, 2003

(54) MEDICATION DELIVERY DEVICE

(75) Inventors: Thomas Buck-Rasmussen, Gentofte (DK); Benny Munk, Hvidovre (DK); Jens Ulrik Poulsen, Virum (DK); Henrik Ljunggren, Ballerup (DK); Peter Møller Jensen, Helsingør (DK); Jens Møller Jensen, Copenhagen (DK)

(73) Assignee: Novo Nordisk A/S, Bagsværd (DK)

(1*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/348,536

(22) Filed: Jul. 7, 1999

Related U.S. Application Data

(60) Provisional application No. 60/098,702, filed on Sep. 1, 1998.

(30) Foreign Application Priority Data

Jul. 8, 1998 (DK)	1996 00909
Nov 17, 1998 (DK)	1998 01500
(51) Int. Cl. 7	A61M 5/00
(52) D.S. Cl.	604/232
(58) Field of Search	604/200-201, 604/228, 232-234

(56) References Cited

U.S. PATENT DOCUMENTS

4,597,753 A * 7/1986 Turley	604/61
4,865,591 A * 9/1989 Sims	604/186
4,936,833 A 6/1990 Sims	
4,973,218 A 11/1990 Holm et al.	
5,137,511 A * 8/1992 Reynolds	604/68
5,226,895 A 7/1993 Harris	
5,364,369 A 11/1994 Reynolds	604/187
5,549,575 A 8/1996 Giambattista et al.	

5,554,125 A * 9/1996 Reynolds	604/187
5,588,251 A 11/1997 Chanoch	
6,146,361 A * 11/2000 DEBiasi et al.	604/232

FOREIGN PATENT DOCUMENTS

EP 0 688 571	12/1995
WO WD 94/21213	9/1994
WO WO 95/13842	5/1995
WO WO 96/02290	2/1996
WO WO 97/49620	12/1997

* cited by examiner

Primary Examiner—Brian L. Caster

Assistant Examiner—Kevin C. Simons

(74) Attorney, Agent, or Firm—Marc A. Began, Esq.; Richard W. Bork, Esq.; Reza Green, Esq.

(57) ABSTRACT

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. At least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The coupling means may be selected from threaded locks, snap locks, hinged locks, or bayonet locks. The medication delivery device is especially suitable for delivering insulin, growth hormone or other medicines.

7 Claims, 2 Drawing Sheets

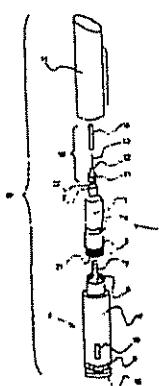


EXHIBIT F



McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive 312 913 0001 phone
 Chicago, Illinois 60606-6709 312 913 0002 fax
www.mbhblaw.com

August 9, 2006

VIA OVERNIGHT COURIER

Stephen J. Vitola
 White & Case LLP
 1155 Avenue of the Americas
 New York, NY 10036-2787

Re: **Novo Nordisk A/S v. sanofi-aventis et al.**
Civil Action No. 05-00645 SLR

Dear Steve:

Please find enclosed additional Aventis production documents. The first two enclosed disks are DVD+R disks. The first DVD+R disk contains documents Bates numbered SAN00764316 through SAN00786484 and the second DVD+R disk contains documents Bates numbered SAN00786485 through SAN00822634 and load files. The third disk is a CD-ROM that contains documents Bates numbered SAN00822635 through SAN00836902 and load files and the fourth disk is a CD-ROM that contains documents Bates numbered SAN00836903 through SAN00837067 and load files.

Aventus's CONFIDENTIAL and HIGHLY CONFIDENTIAL—OUTSIDE COUNSEL EYES ONLY documents are being produced pursuant to Local Rule 26.2 until a protective order is entered. Under Local Rule 26.2, disclosure of these documents should be limited to members and employees of Novo's outside trial counsel who have entered an appearance or have been admitted pro hac vice in this litigation. Aventis's HIGHLY CONFIDENTIAL documents shall not be shared with anyone at Novo at any time, under any circumstances.

Due to the large number of documents in the current production, we will also be producing some additional documents tomorrow, and we currently believe that tomorrow's production will conclude our document production in this litigation. We will, however, supplement our production if more documents come to our attention.

Regards,


 Eric R. Moran
 312 913 3302 direct
 moran@mbhb.com

encls.

EXHIBIT G



US006562011B1

(12) **United States Patent**
Buch-Rasmussen et al.

(10) Patent No.: US 6,562,011 B1
(45) Date of Patent: May 13, 2003

(54) MEDICATION DELIVERY DEVICE

(75) Inventors: Thomas Buch-Rasmussen, Gentofte (DK); Benny Munk, Hvidorre (DK); Jens Ulrik Poulsen, Virum (DK); Henrik Ljunggreen, Ballerup (DK); Peter Møller Jensen, Hørsholm (DK); Jens Møller Jensen, Copenhagen (DK)

(73) Assignee: Novo Nordisk A/S, Bagsværd (DK)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/348,536

(22) Filed: Jul. 7, 1999

Related U.S. Application Data

(60) Provisional application No. 60/098,702, filed on Sep. 1, 1998.

(30) Foreign Application Priority Data

Jul. 8, 1998 (DK)	1998 00909
Nov 17, 1998 (DK)	1998 01500
A61M 5/00	
(51) Int. Cl. 7	604/232
(52) U.S. Cl.	604/200-201,
(58) Field of Search	604/228, 232-234

(56) References Cited

U.S. PATENT DOCUMENTS

4,597,753 A • 7/1986 Turley	604/61
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5,364,369 A • 11/1994 Reynolds	604/187
5,549,575 A 8/1996 Giambattista et al.	

5,554,125 A • 9/1996 Reynolds 604/187
5,688,251 A 11/1997 Chanoch
6,146,361 A • 11/2000 DiBiasi et al. 604/232

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WO	WO 94/21213	9/1994
WO	WO 95/13842	5/1995
WO	WO 96/02290	2/1996
WO	WO 97/49620	12/1997

* cited by examiner

Primary Examiner—Brian L. Casler

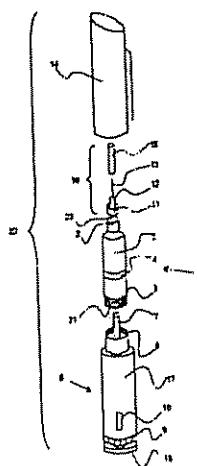
Assistant Examiner—Kevin C. Simmons

(74) Attorney, Agent, or Firm—Marc A. Began, Esq.; Richard W. Bork, Esq.; Reza Green, Esq.

(57) ABSTRACT

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. At least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The coupling means may be selected from threaded locks, snap locks, hinged locks, or bayonet locks. The medication delivery device is especially suitable for delivering insulin, growth hormone or other medicines.

7 Claims, 2 Drawing Sheets



SAN00823009

EXHIBIT H



United States Patent File History

Tab Listings

- A. References (if applicable)
 - A1—U.S. References
 - A2—Foreign References
- B. Jacket (face of file, contents flap, index of claims, PTO 270, searched)
- C. Printed Patent
- D. Specification (serial no. Sheet, abstract, specification, claims)
- E. Oath
 - E1—Small Entity Status (if applicable)
- F. Drawing Figures (if applicable)
- G. USPTO/Applicant Correspondence
- H. Original Patent Application (in cases of FWC)

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PATENT APPLICATION

09348536

J-135 U.S. PTO
09/348536
07/07/99

INITIALS M:TW

CONTENTS

Date received (Incl. C. of M.) or Date Mailed	Date received (Incl. C. of M.) or Date Mailed
1. Application papers.	42. _____
2. Unsigned Dec	43. _____
3. Dec + Surcharge	44. _____
4. ReCncl A	45. _____
5. ReCncl B	46. _____
6. ReCncl B (cont'd)	47. _____
7. ReCncl C	48. _____
8. A.M. (Exos)	49. _____
9. TDS	50. _____
10. Reg Par C.R.	51. _____
11. Filt Optn (3)	52. _____
12. And C.I.	53. _____
13. FINAL REJECT	54. _____
14. EXT Dnce	55. _____
15. Reg for Record (1)	56. _____
16. REJECTION	57. _____
17. Notice of Appeal	58. _____
18. Ext of Time (1)	59. _____
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20. Serial (3)	61. _____
21. Amend D (N.R.)	62. _____
22. Examiner (and I.F.)	63. _____
23. QUERY	64. _____
24. REG PUR (U.R.)	65. _____
25. Priority	66. _____
26. 89.3 Ctg or Add	67. _____
27. Corp. Drawings (2 SITEs) Sct	68. _____
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ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION	MM		7/14/99
O.I.P.E. CLASSIFIER	M-W	5A	7/17 - 99
FORMALITY REVIEW	RF	70556	8-5-99
	RF	70556	10-20-99

INDEX OF CLAIMS

✓ Rejected
 = Allowed
 -- (Through numeral) Canceled
 + Restricted

N Non-elected
 I Interference
 A Appeal
 O Objected

Claim	Final	Original	Date
1	✓	✓	1-22-99
2		✓	1-29-99
3		✓	1-29-99
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SAN00828215

SEARCHED

Class	Sub.	Date	Exmr.
604	200-201 228 232-234	11/1/00	KCS
Same as above		7/17/02	ICCS

**SEARCH NOTES
(INCLUDING SEARCH STRATEGY)**

	Date	Exmr.
M. Bockelman	11/21/00	KCS

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
Same as above		7/17/02	ICCS

(RIGHT OUTSIDE)

SAN00828216

(12) United States Patent
Buch-Rasmussen et al.(10) Patent No.: US 6,562,011 B1
(45) Date of Patent: May 13, 2003

(54) MEDICATION DELIVERY DEVICE

(75) Inventors: Thomas Buch-Rasmussen, Gentofte (DK); Benny Munk, Hvidovre (DK); Jesu Ulrik Poulsen, Vinum (DK); Henrik Ljungqvist, Ballerup (DK); Peter Møller Jensen, Herlev (DK); Jesu Møller Jensen, Copenhagen (DK)

(73) Assignee: Novo Nordisk A/S, Bagsværd (DK)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/348,536

(22) Filed: Jul 7, 1999

Related U.S. Application Data

(60) Provisional application No. 60/096,702, filed on Sep. 1, 1998

(30) Foreign Application Priority Data

Jul. 8, 1998 (DK) 1998 00909
Nov. 17, 1998 (DK) 1998 01500(51) Int. Cl. ⁷ A61M 5/00
(52) U.S. Cl. 604/232
(58) Field of Search 604/200-201, 604/228, 232-234

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5,688,251 A 11/1997 Charnoch
6,146,361 A * 11/2000 DIBbal et al. 604/232

FOREIGN PATENT DOCUMENTS

EP	0 688 571	12/1995
WO	WD 94/21213	9/1994
WO	WD 95/13842	5/1995
WO	WD 96/02290	2/1996
WO	WD 97/09620	12/1997

* cited by examiner

Primary Examiner—Brian L. Caster

Assistant Examiner—Kevin C. Simons

(74) Attorney, Agent, or Firm—Marc A. Began, Esq.; Richard W. Bork, Esq.; Reza Green, Esq.

(57) ABSTRACT

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. At least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The coupling means may be selected from threaded locks, snap locks, hinged locks, or bayonet locks. The medication delivery device is especially suitable for delivering insulin, growth hormone or other medicines.

7 Claims, 2 Drawing Sheets

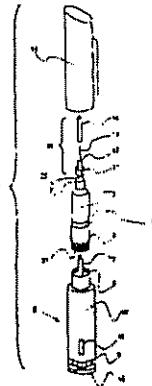


EXHIBIT I

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(2 of 33)

United States Patent

6,146,361

DiBiasi, et al.

November 14, 2000

Medication delivery pen having a 31 gauge needle

Abstract

A *needle* assembly for a medication delivery pen having a *31 gauge needle* cannula that reduces penetration force during an injection process resulting in less pain to the patient without causing any loss in performance or structural integrity.

Inventors: DiBiasi; Michael D. (West Milford, NJ); Harbin; Elizabeth A. (Wayne, NJ); West; Robert E. (Morristown, NJ)

Assignee: Becton Dickinson and Company (Franklin Lakes, NJ)

Appl. No.: 721368

Filed: September 26, 1996

Current U.S. Class:

604/232; 604/272

A61M 005/00

Intern'l Class:

604/232,233,234,272,207,208,211,187

Field of Search:

References Cited [Referenced By]

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EXHIBIT J

United States Patent [19]
Sams

[11] Patent Number: 4,936,833
[45] Date of Patent: Jun. 26, 1990

[54] CARTRIDGE-HOLDER ASSEMBLY FOR MEDICATION DISPENSING UNIT

[75] Inventor: Bernari Sams, London, England

[73] Assignee: Hypoguard (UK) Limited, Woodbridge, England

[21] Appl. No.: 237,147

[22] Filed: Aug. 26, 1988

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 205,198, Jun. 10, 1988, Pat. No. 4,865,391, which is a continuation-in-part of Ser. No. 81,241, Aug. 4, 1987, abandoned.

[51] Int. Cl. 5/24 A61M 5/24
[52] U.S. Cl. 604/232; 604/208; 604/209; 604/220; 222/391

[58] Field of Search 604/68, 72, 208-210, 604/218, 220, 232, 234, 197; 222/325, 340, 391

[56] References Cited

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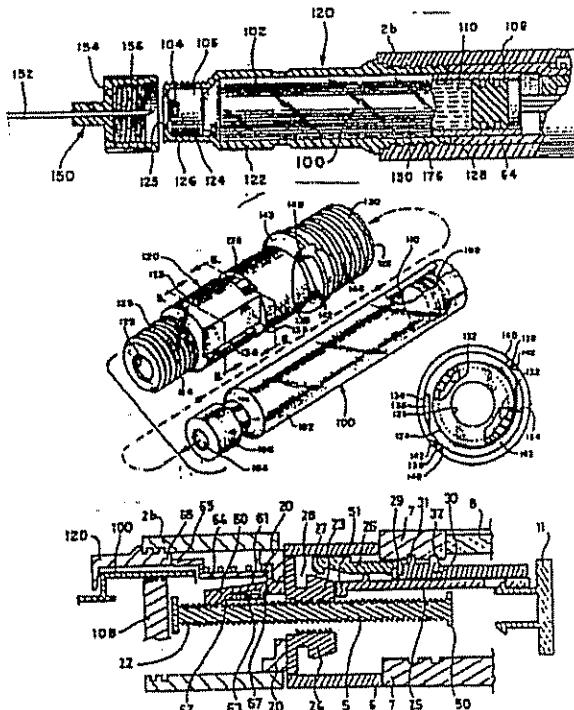
22140 10/1961 German Democratic Rep. 222/391

Primary Examiner—Martin P. Schwadron
Assistant Examiner—Allen J. Flanigan
Attorney, Agent, or Firm—William Brinks Olds Hofer Gilson & Lione

[57] ABSTRACT

A cartridge assembly for a syringe-type medication dispensing unit includes a cartridge having a cartridge body with first and second ends. A pierceable membrane is mounted at the first end and a piston is mounted at the second end, with a volume of medication contained in the cartridge body between the membrane and the piston. A cartridge holder receives the cartridge and defines first and second ends. The first holder end defines a central opening and an external thread for mounting a double-ended needle. The second holder end defines an external thread for securing the holder to a medication dispensing unit and an actuating shoulder. The holder frictionally engages the cartridge to form an assembly which can be handled as a single modular unit with the cartridge held securely in the holder by frictional engagement.

23 Claims, 6 Drawing Sheets



SAN00762258

EXHIBIT K

United States Patent [19]

Reynolds

[11] Patent Number: 5,554,125

[45] Date of Patent: Sep. 10, 1996

[54] PREFILLED VIAL SYRINGE

[76] Inventor: David L. Reynolds, 305 Knowlton Road, P.O. Box 600, (Knowlton) Lac Brome, Quebec, Canada, J0E 1V0

[21] Appl. No.: 245,132

[22] Filed: May 17, 1994

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 791,399, Nov. 16, 1991, Pat. No. 5,364,369, which is a continuation-in-part of Ser. No. 437,203, Nov. 16, 1989, Pat. No. 5,137,527, which is a continuation-in-part of Ser. No. 72,015, Jul. 8, 1987, Pat. No. 4,886,495.

[30] Foreign Application Priority Data

Nov 14, 1990 [GB] United Kingdom 9024710
May 17, 1993 [GB] United Kingdom 9310084

[51] Int. Cl. 6 A61M 5/00

[52] U.S. Cl. 604/187; 604/200; 604/201;
604/203[58] Field of Search 604/82, 87, 88,
604/89, 91, 92, 191, 187, 200, 201, 203,
204, 205, 411, 413, 414, 415, 416, 905,
232, 218, 220

[56] References Cited

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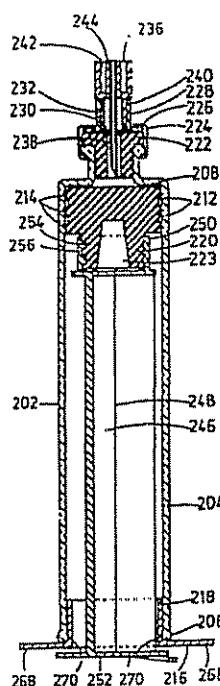
Primary Examiner—Corrine M. Maglione

Assistant Examiner—N. Kent Gring

[57] ABSTRACT

A prefilled syringe for one or two component medicaments is based upon the use of a vial containing a medicament or one component of a medicament, the vial having an open bottom closed by a piston. When a flexible extension of the piston is coupled with a tubular plunger, and an adaptor cap having an internal needle and an external connection for a needle is placed over a cap of the vial, the latter is converted into a prefilled syringe. The open bottom of the vial is configured so as not to interfere with handling of the vials by conventional vial sterilizing, filling and capping machinery, and may be formed so as to provide an internal shoulder which will secure a piston retention member

14 Claims, 9 Drawing Sheets



SAN00762354

EXHIBIT L



US005549575A

United States Patent [19]

Giambattista et al.

[] Patent Number: 5,549,575

[45] Date of Patent: Aug. 27, 1996

[54] CARTRIDGE RETAINER ASSEMBLY FOR
MEDICATION DELIVERY PEN

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5,281,198	1/1994	Haber et al.	604/232
5,360,410	11/1994	Wacks	604/205

[75] Inventors: **Lucio Giambattista**, East Hanover;
Theodore Siuta, Brant Beach, both of
N.J.

Primary Examiner—John D. Yasko
Assistant Examiner—Ronald K. Stright, Jr.
Attorney, Agent, or Firm—Alan W. Fiedler

[73] Assignee: Becton Dickinson and Company,
Franklin Lakes, N.J.

[21] Appl. No.: 304,953

[22] Filed: Sep. 13, 1994

[51] Int. Cl.⁶ A61M 5/00

[51] U.S. Cl. 604/232; 604/206; 604/241

[58] Field of Search 604/232, 234,

604/206-211, 240-243, 181, 187, 199-201,
71, 72, 131-136, 139, 218, 905

[56] References Cited

U.S. PATENT DOCUMENTS

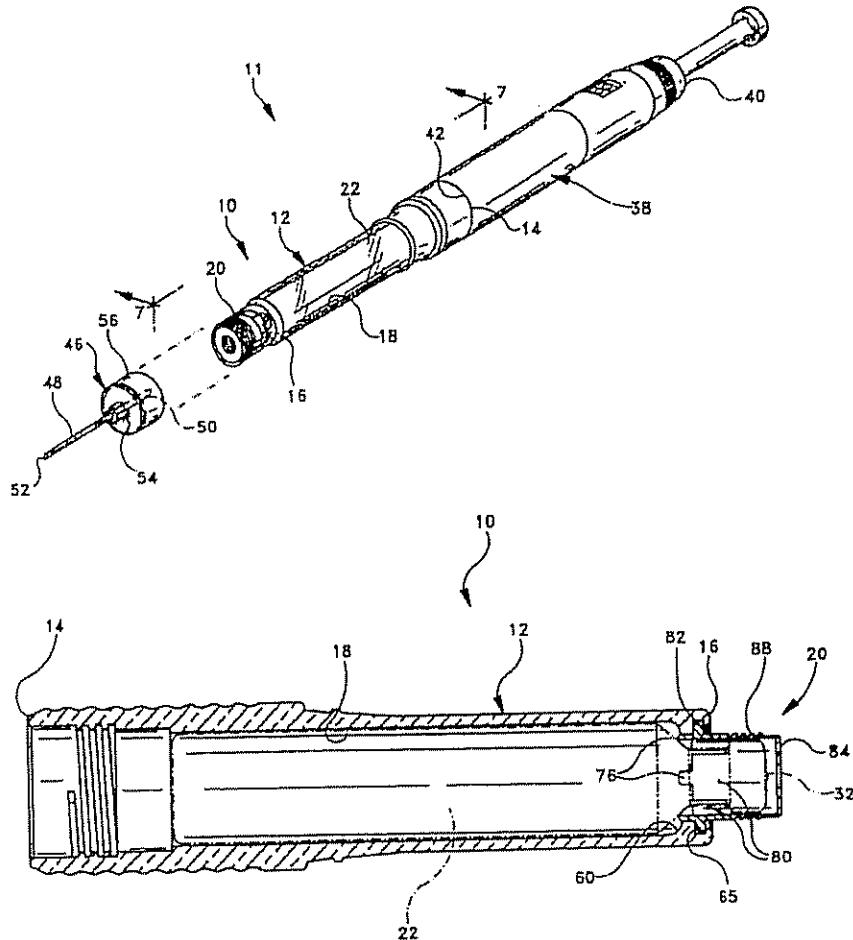
4,973,318 11/1990 Holm et al. 604/208

9 Claims, 5 Drawing Sheets

[57] ABSTRACT

ABSTRACT

A cartridge retainer assembly is provided for a medication delivery pen. The cartridge retainer assembly includes a generally tubular body for receiving, supporting and accurately positioning the body and shoulder portions of a cartridge of medication. A needle mounting collar is floatably mounted to the body of the cartridge retainer assembly for receiving the neck, rubber septum and crimped metallic sleeve of the cartridge. The needle mounting collar will float into a position which compensates for eccentricities and dimensional variations of the cartridge.



SAN00762343

EXHIBIT M



US005137511A

United States Patent [19]
Reynolds

[11] Patent Number: 5,137,511
[45] Date of Patent: Aug. 11, 1992

[54] SYRINGE

[75] Inventor: David L. Reynolds, Montreal, Canada
[73] Assignee: Duoject Medical Systems Inc., Lac Brome, Canada
[21] Appl. No.: 437,203
[22] Filed: Nov. 16, 1989

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 72,015, Jul. 8, 1987, Pat. No. 4,886,495.

[51] Int. Cl.: A61M 5/00
[52] U.S. Cl. 604/88; 604/416; 604/413; 604/191
[58] Field of Search 604/82, 87, 88, 89, 604/91, 92, 191, 200, 201, 413, 414, 416

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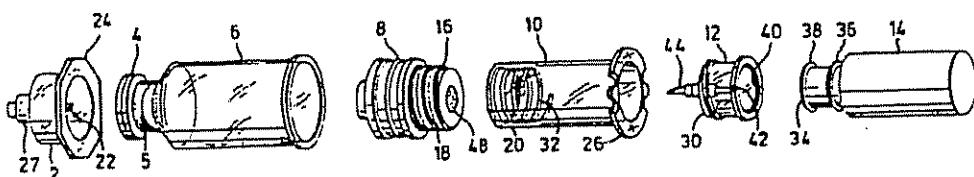
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Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Ralph A. Lewis

[57] ABSTRACT

A prefilled syringe for one or two component medicaments is based upon the use of a vial containing a medicament or one component of a medicament, the vial having an open bottom closed by a piston. When a flexible extension of the piston is coupled with a tubular plunger, and an adaptor cap having an internal needle and an external connection for a needle is placed over a cap of the vial, the latter is converted into a prefilled syringe. The piston may have an axial passage closed by a rescalable septum, so that a separate diluent stored in a flexible capsule may be introduced into the vial through the piston by a double ended needle mounted on a further cap applied to the capsule, the further cap being coupled within the tubular interior of the plunger so that the double ended needle penetrates the septum in the piston. The capsule is pushed forward onto the double ended needle when its contents are to be expelled into the vial. The capsule and its cap are then removed and discarded. In an alternative arrangement, the cap of the capsule is coupled to the adaptor cap and the diluent introduced into the vial through a closure secured by the cap of the vial, after which the capsule is removed from the plunger and the latter is coupled to the piston.

11 Claims, 8 Drawing Sheets



SAN00762289

EXHIBIT N



McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive 312 913 0001 phone
Chicago, Illinois 60606-6709 312 913 0002 fax
www.mbhblaw.com

September 6, 2006

VIA FACSIMILE

Stephen J. Vitola
White & Case LLP
1155 Avenue of the Americas
New York, New York 10036-2787

Re: Novo Nordisk A/S. v. sanofi-aventis et al.
Civil Action No. 05-00646 SLR

Dear Stephen:

I am writing to correct the misstatements of fact contained in your September 1, 2006 letter and confirm the September 1 agreements between Novo and Aventis.

First, it is our recollection that when the parties agreed to extend the deadline to amend pleadings from August 1 to September 1, the extension was specifically requested to allow each party sufficient time to discover facts necessary to support amended pleadings through both document review and depositions. Regardless of Novo's contrary recollection regarding this agreement, however, your continued failure to provide any dates when Novo's witnesses will be available to be deposed is not acceptable. Indeed, even if Novo's witnesses were unavailable to be deposed in August, Novo should have at least provided possible deposition dates in September. As it stands, over one month has passed since Novo was served with deposition notices, and Novo has not provided a single possible day when the depositions could occur.

Second, the assertion that Aventis delayed providing its amended answer to Novo is disingenuous. On Tuesday, August 29, after it was clear that Novo was not going to provide any witnesses during August or even any dates when witnesses would be available, we advised you that Aventis intended to file amended pleadings and sought Novo's consent for the filing. Upon being informed that Novo would not consent to the filing until it had reviewed the amended pleading, we promptly completed drafting the amended pleading and forwarded it to you for review.

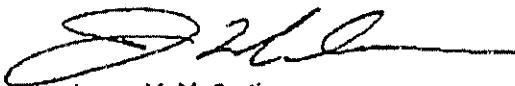
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During our telephone conversations with your office on Friday, September 1, we were informed that Novo was prepared to consent to Aventis's filing on September 1 if Aventis agreed to electronic discovery limitations in the unrelated ITC proceeding between the parties. After Aventis refused to agree to the proposed concessions, Mr. Weingaertner and Mr. Oelke informed us for the first time that Novo would need additional time to review Aventis's amended pleading. Accordingly, we agreed to extend the deadline to amend pleadings from September 1 to September 8. We also emphasized that Aventis would not consider any side deals in connection with Aventis's proposed stipulation for leave to file an amended pleading.

In view of the new September 8 deadline, we would appreciate receiving Novo's decision by the close of business on September 7, 2006. We also look forward to receiving dates when Novo's 30(b)(6) witness and Mr. Began will be available to be deposed.

Sincerely,



James M. McCarthy
312 935 2359 direct
mccarthy@mbhb.com

JMM/ws

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

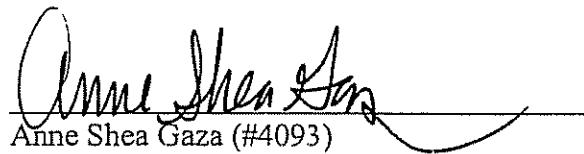
CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2006, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

Steven J. Balick, Esquire
John G. Day, Esquire
Lauren E. Maguire, Esquire
222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19899
302-654-1888

I hereby certify that on November 22, 2006, I have sent by Federal Express the foregoing document to the following non-registered participants:

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UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

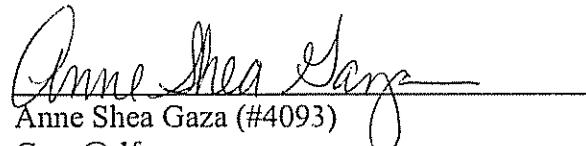
CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2006, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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